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The study follows the guidance set out in Cumitech 31A, Verification and Validation of Procedures in the Clinical Laboratory (American Society for Microbiology), which describes how laboratories can verify performance specifications for new tests or consumables prior to the reporting of patient test results.

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As recommended in Cumitech 31A, for unmodified FDA-approved assays, a minimum of 20 specimens, typically divided equally among positives and negatives, should be included in the study. A caveat regarding the use of only 20 specimens for the verification must be mentioned.

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validation process for clinical microbiology instrumentation Available Resources Although required by CLIA, there are currently no concise guidelines from CLIA or CAP for verification and validation of microbiological procedures. ASM Clinical Microbiology Procedures Handbook, 3rd edition Cumitech 31A: Verification and Validation of

Verification and Validation in Clinical Microbiology

Cumitechs were documents covering the optimal procedures for a variety of clinical microbiology techniques and are now being systemically updated as Practical Guidance for Clinical Microbiology (PGCM). You must be an ASM member to access this content.

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How to Choose QC Strains for Microbial ID Systems ...

Verification vs. Validation • Validation is an on-going process of evaluating test performance over time and is part of a laboratory's quality assurance program ! quality control testing ! internal and/or external proficiency testing ! personnel competency assessments 10

Verification of Antimicrobial Susceptibility Testing ...

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